

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 23

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MICHIO ITO and HIROSHI YAGASAKI

Appeal No. 1998-2836
Application No. 08/453,211

ON BRIEF

Before CALVERT, FRANKFORT, and GONZALES, Administrative Patent Judges.

GONZALES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on an appeal from the examiner's final rejection of claims 1 through 3, 8 through 11 and 16 through 23, which are all of the claims remaining in the application.

We AFFIRM-IN-PART.

Appeal No. 1998-2836
Application No. 08/453,211

The subject matter on appeal is directed to a bone substitute material or sheet and to a method of using a bone substitute material wherein the bone substitute material is "formed by kneading a powdery mixture of animal bone powder and a divalent metal compound together with chitosan sol which is prepared by dissolving chitosan by acid" (specification, p. 4). Claim 1 is illustrative of the subject matter on appeal and is reproduced below:¹

1. A bone substitute material comprising animal bone powder.

The prior art references of record relied upon by the examiner in rejecting the appealed claims are:²

¹ We note that the amendment after final rejection filed on October 11, 1996 (Paper No. 9) has been clerically entered in error. See Paper Nos. 10 and 22. The error should be corrected upon return of the application to the jurisdiction of the examiner.

² We call the following documents (copies enclosed) to the examiner's and to the appellants' attention:

Bell (U.S. Patent No. 4,485,097) teaching a bone-equivalent and a method for preparation thereof comprising, inter alia, demineralized bone powder. See, e.g., col. 6, l. 9 to col. 7, l. 12 and claim 1.

O'Leary et al. (U.S. Patent No. 5,290,558, cited in grandparent application No. 08/015,918) teaching a demineralized bone powder composition disclosed as being
(continued...)

Appeal No. 1998-2836
Application No. 08/453,211

Sumita	5,180,426	Jan. 19, 1993
Oonishi et al. (Oonishi)	5,223,029	Jun. 29, 1993 (filed Apr. 9, 1990)
Ito (published application)	EP 329,098	Aug. 23, 1989

The appealed claims stand finally rejected under 35
U.S.C.

§ 103(a) on the following grounds:

- (1) Claims 1 through 3 and 16 through 23, unpatentable over Ito in view of Oonishi; and
- (2) Claims 8 through 11, unpatentable over Ito in view of Oonishi, and further in view of Sumita.

²(...continued)
useful for reconstruction of skeletal or other osseous defects, bone plates and replacement of corticocancellous strips. See, e.g., col. 2, ll. 6-21 and col. 5, ll. 24-33.

Nagal (Published EPO Application No. 0 253 506) teaching a substitute bone material comprising a ceramic material of natural powdery or particulate hydroxyapatite obtained from cow bones calcined at a temperature around 800°C. See, e.g., col. 3, ll. 24-48 and compare to page 9, lines 4-8 of the appellants' specification. Nagal is particularly relevant to appealed claims 1 and 18.

These referenced documents would appear to us to be worthy of further consideration in the event of any subsequent prosecution before the examiner.

Appeal No. 1998-2836
Application No. 08/453,211

The full text of the examiner's rejections and responses to the arguments presented by the appellants appears in the final rejection (Paper No. 7) and the answer (Paper No. 18), while the complete statement of the appellants' arguments can be found in the main and reply briefs (Paper Nos. 17 and 19, respectively).

OPINION

In reaching our decision in this appeal, we have given careful consideration to the appellants' specification and claims, to the applied prior art references, and to the respective positions articulated by the appellants and the examiner. As a consequence of our review, we have made the determinations which follow.

Rejection (1)

As a preliminary matter, we note that on page 5 of the main brief, the appellants have identified four (4) groupings of claims, namely, (1) claims 1, 2, 8, 9, 11, 16, 17, 20, 22, and 23, (2) claims 3 and 10, (3) claim 18, and (4) claims 19 and 21, with the claims of each group standing or falling together. In accordance with 37 CFR § 1.192(c)(7), we select

claim 1 as being representative of the first grouping, supra, and claims 2, 16, 17, 20, 22 and 23, will stand or fall with claim 1, and claim 19 as being representative of the fourth grouping, supra, and claim 21, will stand or fall with claim 19. We will also address the separate arguments made with respect to claims 3 and 18.

Before addressing the examiner's rejection based upon prior art, it is an essential prerequisite that the claimed subject matter be fully understood. Analysis of whether a claim is patentable over the prior art under 35 U.S.C. §§ 102 and 103 begins with a determination of the scope of the claim. The properly interpreted claim must then be compared with the prior art. Accordingly, we will initially direct our attention to the appellants' claim 1 to derive an understanding of the scope and content thereof.

Independent claim 1 is directed to a bone substitute material comprising animal bone powder. We are informed by the appellants' specification that "[t]he animal bone is mixed in the form of inorganic powder" which is "obtained by firing and pulverizing the animal bones." Specification, p. 8. Specifically, the appellants' specification teaches that the

"animal bones are fired at a temperature between 800EC and 1100EC for 3 through 7 hours to leave inorganic components alone." Id. at 9. After firing, the "inorganic animal bones are pulverized into animal bone powder." Id. Thus, we understand the language "animal bone powder" to include within its scope pulverized inorganic matter derived from animal bones, i.e., animal bones which have been fired to leave the inorganic components of the animal bones alone.

Claim 1 stands rejected under 35 U.S.C. § 103. The guidance provided by our reviewing court in evaluating the issue of obviousness of the invention in view of the teachings of the applied prior art is as follows: The initial burden of establishing a basis for denying patentability to a claimed invention rests upon the examiner. See In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). The question under 35 U.S.C. § 103 is not merely what the references expressly teach but what they would have suggested to one of ordinary skill in the art at the time the invention was made. See In re Young, 927 F.2d 588, 591, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991) and In re Keller, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). While there must be some

Appeal No. 1998-2836
Application No. 08/453,211

suggestion or motivation for one of ordinary skill in the art to combine the teachings of references, it is not necessary that such be found within the four corners of the references themselves; a conclusion of obviousness may be made from common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference. See In re Bozek, 416 F.2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969). Further, in an obviousness assessment, skill is presumed on the part of the artisan, rather than the lack thereof. In re Sovish, 769 F.2d 738, 742, 226 USPQ 771, 774 (Fed. Cir. 1985). Insofar as the references themselves are concerned, we are bound to consider the disclosure of each for what it fairly teaches one of ordinary skill in the art, including not only the specific teachings, but also the inferences which one of ordinary skill in the art would reasonably have been expected to draw therefrom. See In re Boe, 355 F.2d 961, 965, 148 USPQ 507, 510 (CCPA 1966); and In re Preda, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968).

Ito discloses a hardenable composition useful as a filling or cushioning material in dental and orthopedic

fields. See p. 1, ll. 1-3. The composition comprises a sol (a colloidal solution) of acidic aqueous chitosan, hydroxyapatite (hereinafter referred to as "HAp")³ and zinc oxide and/or magnesium oxide in powder form. See p. 2, ll. 14-19 and claim 1.

Oonishi discloses a hardening material useful as a root canal sealer, cement and a filling agent for dental use, or as a bone cement or filling agent. See col. 37, ll. 60-63. The hardening material disclosed by the reference comprises, inter alia, calcium phosphate and a setting liquid, with at least part or the whole of the calcium phosphate powder being either one or both of "-tricalcium phosphate (hereinafter referred to as "-TCP") and tetracalcium phosphate (hereinafter referred to as "4CP"). A residual part of the calcium phosphate powder is taken by HAp, apatite carbonate, \$-tricalcium phosphate (hereinafter referred to as "\$-TCP"), and calcium hydrogen phosphate dihydrate etc. See col. 3, ll. 39-46. Oonishi also teaches that

³ The American Heritage Dictionary of the English Language, Third Edition, (1992), defines "hydroxyapatite" as "[t]he principal bone salt, $\text{Ca}_5(\text{PO}_4)_3\text{OH}$, which provides the compressional strength of vertebrate bone."

The HAp etc. may be calcium phosphate originated from a living body as well as powdered bone or may be a synthetic HAp, apatite carbonate, or β -TCP etc. obtainable from a well-known method or a method known in public. Calcium phosphate of these kinds has no injurious character for a body.⁴

Col. 4, ll. 38-43. We are also informed by Oonishi that β -TCP and 4CP can be converted into HAp under the conditions similar to those in a body or a mouth (col. 1, l. 67-col. 2, l. 2) and that HAp is a main inorganic component of body hard tissue (col. 1, ll. 54-55).

In applying the test for obviousness,⁵ we reach the conclusion that it would have been obvious to one having ordinary skill in the art, from a combined assessment of the Ito and Oonishi teachings, to fabricate the hardenable composition of Ito using the calcium phosphate derived from powdered bone disclosed in Oonishi in place of the HAp powder

⁴ The American Heritage Dictionary of the English Language, Third Edition, (1992), defines "apatite" as "[a] natural, variously colored calcium fluoride phosphate, $\text{Ca}_5\text{F}(\text{PO}_4)_3$, with chlorine, hydroxyl, or carbonate sometimes replacing the fluoride. It is a source of phosphorus for plants and is used in the manufacture of fertilizers."

⁵ The test for obviousness is what the combined teachings of the references would have suggested to one of ordinary skill in the art. See In re Young, supra, and In re Keller, supra.

disclosed in Ito. In our view, the substitution of calcium phosphate derived from powdered bone for HAp in the composition disclosed in Ito would have been obvious to the artisan and the artisan would have had a reasonable expectation of success in doing so based on Oonishi's specific disclosure that calcium phosphate derived from powdered bone and HAp were known equivalents in the art. See, Oonishi, col. 4, ll. 38-43.

As should be apparent from our understanding of the meaning of the language "animal bone powder," supra, it is our opinion that the language "a bone substitute material comprising animal bone powder" reads on the material taught by the combined teachings of Ito and Oonishi because calcium phosphate derived from powdered bone is "animal bone powder" as that language is construed in view of the underlying specification.

Claim 3, dependent from claims 1, 22 and 23, requires both animal bone powder and chemically synthesized particulate HAp. The appellants argue that the applied prior art fails to suggest a bone substitute material containing both animal bone powder and chemically synthesized particulate HAp. See main

brief, p. 15. Notwithstanding the appellants' argument, we have determined, supra, that Oonishi is evidence that calcium phosphate derived from powdered bone, which is "animal bone powder" as broadly defined in the appellants' specification, and synthesized HAp were known to be useful in the art for the same purpose prior to the appellants' invention. Thus, we agree with the examiner that it would have been prima facie obvious to an artisan prior to the appellants' invention to use a combination of calcium phosphate derived from powdered bone and synthesized HAp as the HAp component in the composition disclosed by the Ito reference. See In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Like claim 3, claim 19 requires both animal bone powder and chemically synthesized particulate HAp. In addition, claim 19 recites that "said bone substitute material induces bone formation." The appellants argue (main brief, p. 17) that neither Ito nor Oonishi suggest that substitute bone material comprising animal bone powder can induce bone formation. We do not agree. In fact, Oonishi specifically

teaches (Table 9) that his Example 25 induces bone growth.⁶
See, also, Oonishi, col. 13, ll. 29-43.

At any rate, for the reasons set forth above, the applied prior art would have suggested to the artisan a bone substitute material having the composition recited in claim 19. We can perceive of no reason why the composition suggested by the prior art would not have also induced bone formation. The mere recognition of latent functions or properties possessed by a prior art process cannot serve as the basis for patentably distinguishing over that prior art process. See Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 633, 2 USPQ2d 1051, 1054 (Fed. Cir. 1987), cert. denied, 484 U.S. 827 (1987). Note also In re Baxter Travenol Labs, 952 F.2d 388, 392, 21 USPQ2d 1282, 1285 (Fed. Cir. 1991) ("[m]ere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention") and Ex parte Obiaya, 227 USPQ 58, 60 (Bd. App. 1985), aff'd. mem., 795 F.2d 1017 (Fed. Cir. 1986) ("[t]he fact that appellant has

⁶ The pathological remarks regarding example 25 indicate that "[a]fter 4 weeks, a number of bone cells existed" and "[a]fter 6 weeks, the bone increased in amount."

recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious.")

Having determined that the prior art itself reasonably establishes a prima facie case of obviousness of claims 1, 3 and 19, we will now consider the evidence asserted to support the patentability of the claimed invention, namely, the comparative tests found in the specification and the declaration under 37 CFR § 1.132 of one of the inventors, Michio Ito (see attachment to Paper No. 6), a copy of which is attached to the main brief.⁷

⁷ The examiner bears the initial burden of presenting a prima facie case of obviousness (see In re Rijckaert, supra). Once a prima facie case is established, any evidence supporting the patentability of the claimed invention, such as any evidence in the specification or any other evidence submitted by the applicant must be considered. The ultimate determination of patentability is based on the entire record, by a preponderance of evidence, with due consideration to the persuasiveness of any arguments and any secondary evidence. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). All the evidence on the question of obviousness must be considered. In re Piasecki, 745 F.2d 1468, 1471, 223 USPQ 785, 787 (Fed. Cir. 1984).

The appellants assert that they have discovered that bone substitute material containing bone powder induces bone formation at a rate that is at least twice the rate observed with a bone substitute material that contains apatite but does not contain animal bone powder. In support, the appellants refer to pages 8, 10, 14, 15 and 21 of the specification. In addition, the declaration under 37 CFR § 1.132 purportedly shows that a bone substitute material containing chitosan and bovine bone powder is more effective in promoting new bone growth than a bone substitute material containing chitosan and HAp. See main brief pages 13-15.

Assuming arguendo that the comparative tests contained in the specification support the appellants' assertions of superior results and that those results were unexpected, we do not find the assertions to be convincing of the patentability of the claimed subject matter. First, the appellants have not established that the tests provide a comparison with the closest prior art. See In re Baxter Travenol Labs., 952 F.2d 388, 392, 21 USPQ2d 1281, 1285 (Fed. Cir. 1991); In re De Blauwe, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984). It appears that the closest prior art is the Ito reference,

which teaches a hardenable composition containing chitosan sol, commercially available HAp⁸ and zinc oxide and/or magnesium oxide powder. Specifically, Ito discloses an Example No. 5 comprising 1.0 g chitosan solution, .46 g HAp, .03 g zinc oxide, and .01 g calcium oxide having a hardening time of 2 min and a compressive strength of 21.6 kg/cm². The 37 CFR § 1.132 declaration states that the reported experiments were performed on samples manufactured as described on pages 14 and 15 of the appellants' specification. Page 14 of the specification describes a sample containing bovine bone powder and HAp. A sample containing "a small amount of hydroxyapatite without any bovine bone powder" is described on page 15. The specification does not identify what constitutes "a small amount of hydroxyapatite" or whether all types of commercially available HAp were tested. The samples containing apatite, rather than HAp, are even more unlike the composition disclosed in Ito. Thus, the evidence

⁸ Based on Oonishi's reference to "synthetic HAp," we understand that "commercially available hydroxyapatite" also includes natural HAp, i.e., HAp derived from a living body or from powdered bone.

Appeal No. 1998-2836
Application No. 08/453,211

before us does not establish that superior results have been demonstrated over the closest prior art.

Second, the evidence presented in the declaration is not commensurate in scope with the claims. See In re Grasselli, 713 F.2d 731, 743, 218 USPQ 769, 778 (Fed. Cir. 1983); In re Clemens, 622 F.2d 1029, 1035, 206 USPQ 289, 296 (CCPA 1980). The appellants' claim 1 encompasses the use of any animal bone powder, but comparative tests are presented only for bovine bone powder. We find in the evidence of record no reasonable basis for concluding that the great number of materials encompassed by the appellants' claims would behave as a class in the same manner as the particular material tested. See In re Lindner, 457 F.2d 506, 508, 173 USPQ 356, 358 (CCPA 1972); In re Susi, 440 F.2d 442, 445-46, 169 USPQ 423, 426 (CCPA 1971). In addition, unlike the "superior" sample described in the specification, claim 1 does not require both bovine powder and HAp. For the foregoing reasons, the rebuttal evidence is given little weight.

The appellants argue that the examiner has misconstrued column 4, lines 38-42 of the Oonishi reference and that the cited text does not suggest that HAp and animal bone powder

are equivalent. Rather, as the appellants see it, the cited text teaches that the "residual component" or the "HAp etc." can be: (1) calcium phosphate derived from a living body, (2) calcium phosphate derived from powdered bone, (3) synthetic HAp, (4) apatite carbonate, or (5) β -TCP. See main brief, p. 8.

We are not persuaded by this argument that the standing 35 U.S.C. § 103 rejection of claims 1, 3 and 19 is in error. Even if the appellants' interpretation is correct, it is our opinion that the cited text would have suggested the equivalency of calcium phosphate derived from powdered bone and synthetic HAp. Thus, prior to the appellants' invention, it would have been obvious to use either calcium phosphate derived from powdered bone or synthetic HAp as the commercially available HAp in the composition taught by Ito. As we have indicated, supra, calcium phosphate derived from powdered bone is "animal bone powder."

The appellants' argument (main brief, pp. 9-11) that Oonishi teaches away from the Ito composition because Ito teaches HAp as a major component and Oonishi teaches HAp as a residual component is also not well taken. The fact that

calcium phosphate derived from powdered bone or animal bone powder is present as a residual component in the composition disclosed by Oonishi does not teach away from the substitution of calcium phosphate derived from powdered bone for HAp in the composition disclosed by Ito, since Oonishi is not relied on for its teaching of the proportion of HAp in a hardenable composition but only for its teaching of the interchangeability of calcium phosphate derived from powdered bone and synthetic HAp in a hardenable composition of the type disclosed by Ito.

The appellants also argue (main brief, pp. 11-12) that even if Oonishi suggests the inclusion of powdered bone and HAp in the same group of substances useful for the residual component in Oonishi's composition, such is not a teaching that HAp and animal bone powder are "equivalent" in the Ito composition. This argument is not well taken because, in our opinion, the evidence of record establishes that an artisan would have understood that calcium phosphate derived from powdered bone is mainly HAp. We note every reference relies to some extent on knowledge of persons skilled in the art to complement that which is disclosed therein. See In re Bode,

Appeal No. 1998-2836
Application No. 08/453,211

550 F.2d 656, 660, 193 USPQ 12, 16 (CCPA 1977). Moreover, artisans must be presumed to know something about the art apart from what the references disclose (see In re Jacoby, 309 F.2d 513, 516, 135 USPQ 317, 319 (CCPA 1962)) and the conclusion of obviousness may be made from "common knowledge and common sense" of the person of ordinary skill in the art (see In re Bozek, supra). It was known in the art prior to the appellants' invention that HAp is a main inorganic component of bone (see Oonishi at col. 1, ll. 54-55 and the definition of "hydroxyapatite" in The American Heritage Dictionary of the English Language, supra). Therefore, we conclude that the artisan would have understood that calcium phosphate derived from powdered bone is mainly HAp and that its use in the composition of Ito would have been an obvious alternative to synthetic HAp.

Finally, the appellants argue (main brief, pp. 12-13) that Oonishi fails to provide any motivation for producing a hardenable material comprising bone powder. We are not persuaded by this argument because a teaching of equivalency in the prior art is itself enough to support a rejection under 35 U.S.C.

Appeal No. 1998-2836
Application No. 08/453,211

§ 103. See In re Ruff, 256 F.2d 590, 599, 118 USPQ 340, 348 (CCPA 1958).

Thus, it is our conclusion that, on balance, the evidence and arguments provided by the appellants fail to outweigh the evidence of obviousness established by the prior art. This being the case, we will sustain the examiner's rejection of claims 1, 3 and 19. Since claims 2, 16, 17, 20, 22 and 23 stand or fall with independent claim 1 and claim 21 stands or falls with claim 19, supra, it follows that we will also sustain the standing

35 U.S.C. § 103(a) rejection of those claims.

Claim 18, dependent from claims 16 and 17, requires, inter alia, that the animal bone powder be bovine bone powder. Neither Ito nor Oonishi teaches or suggests bovine bone powder or calcium phosphate derived from powdered bovine bone. Apparently realizing this, the examiner cites page 8, lines 8-13 of the appellants' specification for its teaching that the source of the animal bone powder may be from a wide variety of animals living on the land and under the sea. The examiner then "takes Official Notice" of the equivalence of bone powder derived from a wide variety of animals living on the land and

under the sea. This position, however, represents a conclusion which is based on a statement of equivalency in the appellants' own disclosure. In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on the applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. In re Ruff, supra. It is well settled that in order to establish a prima facie case of obviousness the prior art teachings must be sufficient to suggest to one of ordinary skill in the art making the modification needed to arrive at the claimed invention. See, e.g., In re Lulu, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1984). The examiner has supplied no factual basis in the applied prior art to support his legal conclusion of obviousness. Thus, we will not sustain the examiner's rejection of claim 18 under 35 U.S.C. § 103 based on Ito and Oonishi.

Since the prior art relied on by the examiner fails to establish a prima facie case of obviousness of claim 18, we need not consider the appellants' evidence of nonobviousness

Appeal No. 1998-2836
Application No. 08/453,211

with respect to this claim. In re Fine, 837 F.2d 1071, 1076,
5 USPQ2d 1596, 1600 (Fed. Cir. 1988).

Rejection (2)

We note that the appellants have not argued the merits of the rejection of claims 8, 9 and 11 apart from the rejection of claim 1, or the rejection of claim 10 apart from the rejection of claim 3. Therefore, claims 8, 9 and 11 stand or fall with claim 1 and claim 10 stands or falls with claim 3. See In re Nielson, 816 F.2d 1567, 1572, 2 USPQ2d 1525, 1528 (Fed. Cir. 1987) and the appellants' grouping of claims at page 5 of the main brief. Accordingly, we will also sustain the standing 35 U.S.C. § 103(a) rejection of claims 8 through 11 as unpatentable over Ito in view of Oonishi, and further in view of Sumita.

CONCLUSION

To summarize, the examiner's decision to reject claims 1 through 3, 8 through 11, 16, 17 and 19 through 23 under 35 U.S.C. § 103 is affirmed. The examiner's decision to reject claim 18 under 35 U.S.C. § 103 is reversed.

Appeal No. 1998-2836
Application No. 08/453,211

The decision of the examiner is affirmed-in-part.

No time period for taking any subsequent action in
connection with this appeal may be extended under 37 CFR
§ 1.136(a).

AFFIRMED-IN-PART

IAN A. CALVERT)
Administrative Patent Judge)
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Appeal No. 1998-2836
Application No. 08/453,211

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